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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/400,365	09/20/1999	FADY T. CHARBEL	76461	3361

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EXAMINER
JONES, HUGH M

ART UNIT	PAPER NUMBER
2123	23

DATE MAILED: 07/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/400,365	Charbel et al.
Examiner	**Art Unit**
Hugh Jones	2123

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Apr 3, 2003* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-28 and 52-55* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-28 and 52-55* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *Apr 3, 2003* is/are a) ☐ accepted or b) ☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Introduction

1. Claims 1-28 and 52-55 of U. S. Application 09/400,365 filed on 20-September-1999, are pending. This action is responsive to 4/3/2003.

Specification

2. The amendment filed 4/3/2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicants have not indicated support for the new figure. Applicant is required to cancel the new matter in the reply to this Office Action or show support for the figure in the original specification.

Priority

3. Applicants state (page 11, paper # 21) that:

> "In a previous office action, the Kamm reference (U.S. Patent 6,117,087) was properly withdrawn as a prior art reference in the view of the effective filing date of the then pending claims of February 3, 1998. Applicant neither admits nor denies the prior art status of the Kamm reference, but hereby withdraws the claim to priority based on the February 3, 1998 filing date for the presently pending claims as amended. ... Applicants expressly reserves the right to reassert the claim for priority based upon the Feburary 3, 1998 filing date in this or a later-filed application."

4. The Examiner requests unambiguous clarification of Applicant's filing date so that the Examiner can properly examine the application in a compact and timely fashion. It is noted that the 102(e) rejection based on Kamm was withdrawn in view of Applicant's claim to the 2/3/1998 priority. Applicants consequently withdrew the claim to priority after the 102(e) prior art was withdrawn. Hence, the Kamm rejection is reasserted.

5. *If applicant desires priority under 35 U.S.C. based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application.* This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application. ***Conversely, If applicant desires to withdraw priority under 35 U.S.C. based upon a previously filed copending application, specific reference to the earlier filed application must be deleted in the instant application (see Applicant's amendment "B" - paper # 8).***

Claim Rejections - 35 USC § 103

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Before setting forth the rejection below, a short discussion of the art is in order. Applicant's IDS has set forth the following references that this examiner considers to be pertinent in the present application:

a. "Predictive Value of a Computerized Model for the Cerebral Circulation," (Poster Abstract) a presentation apparently made at the 44th Annual Meeting of Congress of Neurological Surgeons in October of 1994 [previously dubbed as "Charbel #2" in the prior Office Action]; and

b. "Validation and Clinical Potential of a Computerized Model of the Cerebral Circulation," (Poster Abstract) a presentation apparently made at the first Annual Meeting of the Joint Section on Cerebrovascular Surgery of the American Association of Neurological Surgeons and the Congress of Neurological Surgeons in January of 1996 [previously dubbed as "Charbel #1" in the prior Office Action.

8. Looking at the authors of these presentations, it is apparent that two of the named inventors in the present application were working on the materials in at least two of these presentations more than a year prior to the filing of the provisional application from which the

current application depends (i.e., February 3, 1998). Furthermore, it is apparent from reading the abstracts that the work presented in 1996 [previously dubbed Charbel #1] was an extension of the work presented in 1994 [previously dubbed Charbel #2]. More specifically, the abstract from the 1994 presentation states, in part, "[W]e find the predictive value of this model promising. In vivo validation is currently underway." Unsurprisingly, the presentation made in 1996 is a "direct in vivo validation of the [computer] model." Though the authors (i.e., the "inventive entities") of these presentations are not exactly the same, three of the listed authors remained consistent (i.e., Charbel, Clarke, Ausman). Consequently, these two presentations are hereby considered to be one "teaching" (i.e., the 1996 validation procedures used the computer modeling disclosed in the 1994 presentation).

9. The Examiner's attempt to verify this inference in a Rule 105 request in the previous office Action did not produce any more guidance from the applicant. However, due to the direct correlation between the abstracts themselves, it is this examiner's belief that the two presentations are directed to the same computer simulation model disclosed in the 1994 presentation. Thus, it is on this proposition that the following rejection is based. For convenience, these two presentations will be referred to simply as "Charbel et al." hereinafter.

10. Claims 1-4, 10-14, 20, 22-24 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Charbel et al., as discussed above, or Kamm et al., in view of any of Clark et al. (1989, pp. 217-230 - of record) or Himwich et al. (1965, pp. 164-172 - of record) or Himwich et al. (1974 - of record).

11. Charbel et al. discloses a computer program and method for simulating surgical procedures on a patient that alters circulation systems. The computer program is for any multivesseled network configuration, including the Circle of Willis, as well as surgical anatomoses supplied to the vessels. The computer program applies one-dimensional, explicit, finite-difference algorithm based on a conservation of mass equation, a Navier-Stokes momentum equation, and an equation of state relating local pressure to size of artery to obtain computerized model of the cerebral circulation and its concurrent simulation results. The simulation includes forcing the model by one or more pressure- or flow-time signatures. (1994 presentation abstract: p. 166, §27.) The computerized model is specifically tailored to "any distensible vessels of various shapes, lengths and configurations" that is "reconfigured to include stenoses, bypasses and natural or imposed anatomoses" (i.e., surgical perturbations) thereby "reproducing each patient's individual anatomy." (1996 presentation abstract: p. 113, col. 1, Par. 1.) The calculated flow and the measured flow are then compared to validate the accuracy of the computer model to the actual patient including a "remodeling procedure" (i.e., to correct for any discrepancies observed between the predicted and actual values). (1996 presentation abstract: p. 113, col. 2, lns. 11-15.).

12. Kamm et al. disclose a method and apparatus for deriving a physiological description and clinically-useful data reboarding the cardiovascular system of an individual subject. The method includes obtaining a measurement sample associated with cardiovascular flow and utilizing a model, which may be distributed and/or non-linear to derive a description and data. The model

generates and uses functions of source parameters and may, in an embodiment, match measurement samples against a library of stored predicted samples. A best-matching, predicted sample may then be associated with a measurement sample. An apparatus is provided which, according to an embodiment, includes an input for obtaining a measurement sample, a processor to derive the description and data, and an output. The apparatus may also include a digital storage medium to store a library of predicted samples. In particular, Kamm et al. disclose a computerized modeling simulation system that takes a general model of an arterial circulatory network and modifies the general model with specific parameters of a patient for a more accurate model/simulation specific for that patient as recited in the claims. See at least col. 1, lines 25-26, 36-47, 60-65; col. 2, lines 4-6; col. 3, lines 6-10, 35-37, 45-68; col. 4, lines 1-6, 23-28; col. 8, lines 49-50, 54-56; col. 9, lines 10-11; col. 10, lines 33-35, 49-54; col. 13, lines 25-26.

13. The base references do not expressly disclose calibrating the flow resistance by using a ratio of measured and calculated flows.

13. **Clark et al. (1989, pp. 217-230) or Himwich et al. (1965, pp. 164-172) or Himwich et al., 1974)** disclose the use of corrections or fitting parameters to calibrate the blood flow resistance to correspond to individual differences between patients. See Clark 1989 at page 220; Himwich 1965 at page 167; Himwich 1974 at section D (Resistance Adjustment).

14. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the base reference to include calibrating the flow resistance by using a ratio of measured and calculated flows for the following reasons. Any realistic simulation of blood flow

in humans must account for individual differences in blood flows. The blood flow models are based upon equivalent RC circuit network models. A particular blood flow is associated with each simulation including the simulation parameters. Fitting parameters are required change the flow resistance in the model to ensure that the blood flow corresponds to "real-life" blood flows in different individuals. The use of the "ratios" is merely the implementation of fitting parameters to calibrate the blood flow to correspond to a particular set of circumstances.

15. Claims 5-7, 25-28 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Charbel et al., or Kamm et al., as discussed above, in view of any of Clark et al. (1989, pp. 217-230) or Himwich et al. (1965, pp. 164-172) or Himwich et al., 1974) and in further view of any of Karplus or Foutrakis, both previously cited by the examiner.

16. Charbel et al. discloses a computer program and method for simulating surgical procedures on a patient that alters circulation systems. The computer program is for any multivesseled network configuration, including the Circle of Willis, as well as surgical anatomoses supplied to the vessels. The computer program applies one-dimensional, explicit, finite-difference algorithm based on a conservation of mass equation, a Navier-Stokes momentum equation, and an equation of state relating local pressure to size of artery to obtain computerized model of the cerebral circulation and its concurrent simulation results. The simulation includes forcing the model by one or more pressure- or flow-time signatures. (1994 presentation abstract: p. 166, §27.) The computerized model is specifically tailored to "any distensible vessels of various shapes, lengths and configurations" that is "reconfigured to include

stenoses, bypasses and natural or imposed anatomoses" (i.e., surgical perturbations) thereby "reproducing each patient's individual anatomy." (1996 presentation abstract: p. 113, col. 1, Par. 1.) The calculated flow and the measured flow are then compared to validate the accuracy of the computer model to the actual patient including a "remodeling procedure" (i.e., to correct for any discrepancies observed between the predicted and actual values). (1996 presentation abstract: p. 113, col. 2, lns. 11-15.).

17. Kamm et al. disclose a method and apparatus for deriving a physiological description and clinically-useful data reboarding the cardiovascular system of an individual subject. The method includes obtaining a measurement sample associated with cardiovascular flow and utilizing a model, which may be distributed and/or non-linear to derive a description and data. The model generates and uses functions of source parameters and may, in an embodiment, match measurement samples against a library of stored predicted samples. A best-matching, predicted sample may then be associated with a measurement sample. An apparatus is provided which, according to an embodiment, includes an input for obtaining a measurement sample, a processor to derive the description and data, and an output. The apparatus may also include a digital storage medium to store a library of predicted samples. In particular, Kamm et al. disclose a computerized modeling simulation system that takes a general model of an arterial circulatory network and modifies the general model with specific parameters of a patient for a more accurate model/simulation specific for that patient as recited in the claims. See at least col. 1, lines 25-26,

36-47, 60-65; col. 2, lines 4-6; col. 3, lines 6-10, 35-37, 45-68; col. 4, lines 1-6, 23-28; col. 8, lines 49-50, 54-56; col. 9, lines 10-11; col. 10, lines 33-35, 49-54; col. 13, lines 25-26.

18. The cited art discloses the recited invention as discussed above. However, said art does not teach how the specific parameters are collected, i.e., obtaining boundary measurements (e.g., diameter of the vessel and tracing ends of the vessel) using image/pixel analysis to determine the measurements of the vessels of the living subject. Karplus, previously cited and applied in a prior office Action, teaches obtaining boundary and cross-section information of specified vessels using MRI technology for the purpose of inputting the gathered information into a circulation simulator for generating a specific simulation result for a specific patient. (p. 38, §3.2) Foutrakis, previously cited and applied in a prior Office Action, teaches obtaining boundary and cross-section information of specified vessels using MRI technology for the purpose of inputting the gathered information into a circulation simulator for generating a specific simulation result for a specific patient. (Abstract; p. 4; Figure 7; p. 12) It would have been obvious for one of ordinary skill in the art at the time of the invention to have used Magnetic Resonance Imaging technology to obtain the specific parameters of a specific vessel as taught by Karplus and Foutrakis to be used in the simulation as taught by the base references because the base references already teach tailoring a simulation using specific parameters of a vessel of a patient and Karplus/Foutrakis both teach it is well know to obtain such information using MRI technology in the manner recited.

19. Claims 15-18, 52, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charbel et al., or Kamm et al., as applied above, in view of any of Clark et al. (1989, pp. 217-230) or Himwich et al. (1965, pp. 164-172) or Himwich et al., 1974) and in further view of Charbel et a1. (1997 presentation abstract), cited by the Applicant.

20. As to claims 15, 52, and 55, the cited art discloses the recited invention as discussed above. In particular, said art specifically teaches that direct flow measurements were obtained. However, the cited art does not specifically teach that PCMRA (Phase Contract Magnetic Resonance Angiography) flow measurement techniques were used.

21. Charbel et al. ("Phase Contract MR Flow Measurement System Using Volumetric Flow Contrainted Image Interpolation and Color Coded Image Visualization", Poster Abstract of a presentation made at the 47th Annual Meeting of Congress of Neurological Surgeons in September/October of 1997) discloses that PCMRA was available in 1997 to measure blood flow in a patient. Moreover, various other non-intrusive flow measurement systems were already available at the time the invention was made (e.g., Doppler). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used PCMRA to obtain the flow measurement since it was known to one of ordinary skill in the art that non-invasive measurement techniques were available, and PCMRA was purported to provide a more accurate flow measurement result than the other options as taught in Charbel et al. (1997 presentation abstract).

22. As to claims 16-18, Charbel et al. (1997 presentation) teaches that PCMRA can also be used to obtain cross-section measurements as well. (1997 presentation abstract: p. 377, Introduction, lines 4-6). As to localizing and tracing three dimensional images of a vessel to obtain the measure, these steps are inherent in obtaining vessel measurements using image analysis (See Karplus and Foutrakis, cited and applied above) and therefore is considered to be inherent in Charbel et al. (1997 presentation abstract).

23. Claims 53 and 54 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Charbel et al. or Kamm et al. in view of any of Clark et al. (1989, pp. 217-230) or Himwich et al. (1965, pp. 164-172) or Himwich et al., 1974) and in further view of either Karplus or Ortega ("Predicting Cerebral Aneurysms with CFD"), previously cited.

24. The cited art teaches the recited invention as applied above. Though said art teaches obtaining flow measurement, it does not teach that the flow measurements were obtained by Doppler measurements.

25. Karplus, as discussed above, teaches using Doppler flow measurements to correct and validate simulation results. (p. 40, col. 2, Par. 4)

26. Ortega discloses using Doppler flow measurements to be used in Computational Fluid Dynamics simulation (CFD).

27. It would have been obvious for one of ordinary skill in the art at the time of the invention to have used Doppler technology to correct and validate simulation results as taught by Karplus/Ortega in the simulation as taught by Charbel et al. or Kamm et al. because

Karplus/Ortega teaches that such correction/validation techniques using Doppler is well known to one of ordinary skill in the art to verify predicted results with actual results and non-invasive technology is always preferred.

Response to Arguments

28. Applicant's arguments filed 4/3/2003 have been fully considered but they are not persuasive.

29. Applicants arguments (page 10, paper # 21) relating to "remodeling" and alleged known meanings for terms are conclusory and are not persuasive. Argument does not replace evidence where evidence is necessary. Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art. The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration.

30. Applicants state (page 11, paper # 21) that:

"In a previous office action, the Kamm reference (U.S. Patent 6,117,087) was properly withdrawn as a prior art reference in the view of the effective filing date of the then pending

claims of February 3, 1998. Applicant neither admits nor denies the prior art status of the Kamm reference, but hereby withdraws the claim to priority based on the February 3, 1998 filing date for the presently pending claims as amended. ... Applicants expressly reserves the right to reassert the claim for priority based upon the Feburary 3, 1998 filing date in this or a later-filed application."

31. The Examiner requests unambiguous clarification of Applicant's filing date so that the Examiner can properly examine the application in a compact and timely fashion. It is noted that the 102(e) rejection based on Kamm was withdrawn in view of Applicant's claim to the 2/3/1998 priority. Applicants consequently withdrew the claim to priority after the 102(e) prior art was withdrawn. Hence, the Kamm rejection is reasserted.

32. Any inquiry concerning this communication or earlier communications from the examiner should be:

directed to:

> Dr. Hugh Jones telephone number (703) 305-0023, Monday-Thursday 0830 to 0700 ET, ***or*** the examiner's supervisor, Kevin Teska, telephone number (703) 305-9704. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, telephone number (703) 305-3900.

mailed to:

> Commissioner of Patents and Trademarks
> Washington, D.C. 20231

or faxed to:

> (703) 308-9051 (for formal communications intended for entry) ***or***

(703) 308-1396 (for informal or draft communications, please label "*PROPOSED*" or "*DRAFT*").

Dr. Hugh Jones

Primary Patent Examiner

June 29, 2003